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ABSTRACT

In fiscal year 2001, federal agencies provided $19 billion for university research, a vital part of the nation's research and development effort. GAO was asked to examine federal agencies' actions to ensure that (1) the results of the university research grants they fund are made available to the public and (2) universities receiving such grants implement policies for identifying and managing possible financial conflicts of interest. GAO reviewed the actions of eight federal agencies and conducted a Web-based survey of 200 leading research universities. GAO also met with officials in the Office of Science and Technology Policy to discuss the National Science and Technology Council's role in coordinating federal science policy. This report explains the study in detail. (Author)

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United States General Accounting Office

GAO

Report to the Honorable Richard C. Shelby, U.S. Senate

November 2003

UNIVERSITY RESEARCH

Most Federal Agencies Need to Better Protect against Financial Conflicts of Interest

ED 482 980

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Highlights

Highlights of GAO-04-31, a report to the Honorable Richard C. Shelby, U.S. Senate

UNIVERSITY RESEARCH

Most Federal Agencies Need to Better Protect against Financial Conflicts of Interest

Why GAO Did This Study

In fiscal year 2001, federal agencies provided $19 billion for university research, a vital part of the nation's research and development effort. GAO was asked to examine federal agencies' actions to ensure that (1) the results of the university research grants they fund are made available to the public and (2) universities receiving such grants implement policies for identifying and managing possible financial conflicts of interest. GAO reviewed the actions of eight federal agencies and conducted a Web-based survey of 200 leading research universities. GAO also met with officials in the Office of Science and Technology Policy (OSTP) to discuss the National Science and Technology Council's role in coordinating federal science policy.

What GAO Recommends

GAO recommends that the Department of Education post the final technical reports of the research it funds on its Web site. GAO also recommends that the National Science and Technology Council coordinate the development of a uniform federal requirement for identifying and resolving financial conflicts of interest in federally funded research. In commenting on the draft report, Education agreed with the recommendation to post research results on its Web site. OSTP agreed with the recommendation for developing a federal requirement.

www.gao.gov/cgi-bin/getrpt?GAO-04-31.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robin Nazzaro at (202) 512-3841or nazzaror@gao.gov.

What GAO Found

Each of the eight federal agencies GAO examined relies on university scientists who receive federally funded research grants to make the results available to the public. Although university scientists customarily seek to publish their research results in peer-reviewed journals, agencies cannot require such publication as a condition for funding because it is impossible to ensure in advance that the results will be accepted for publication. Agencies do, however, explicitly encourage funding recipients to make results public. The Departments of Agriculture, Defense, and Energy; the Environmental Protection Agency (EPA); and the National Aeronautics and Space Administration (NASA) also disseminate the results of their funded research by posting them on their Web sites (see table below). Officials from these agencies said that posting the results is an effective way to share information among scientists, as well as with the public. In contrast, the National Institutes of Health (NIH) and the National Science Foundation (NSF) do not post research results on their Web sites. According to NIH officials, the risk associated with posting researchers' final reports before they have been validated by peer review is too great in the biomedical field. The Department of Education is considering how best to widely disseminate the results of research it funds.

NIH and NSF are the only federal agencies that require universities to implement policies for identifying and managing possible financial conflicts of interest for the research they fund. The other six agencies do not have financial conflict of interest standards for university research grants. Of the 171 universities that responded to the GAO survey, 148 (87 percent) reported that all of their federally funded research is covered by financial conflict of interest policies that are consistent with either NIH's or NSF's standards. However, 17 universities reported that they do not extend either agency's requirements to cover research grants from other federal agencies. Unless federal agencies uniformly require that universities implement conflict of interest policies, the government cannot properly safeguard against financial conflicts of interest that might bias federally funded research.

Agencies That Post Research Results on Their Web Sites

Agency	Web-based information system	Information posted
Agriculture	Current Research Information System	Annual and final technical reports
Defense	Defense Technical Information Center	Final technical reports
Energy	Information Bridge	Final technical reports
EPA	National Center For Environmental Research	Annual and final report summaries
NASA	Scientific and Technical Aerospace Reports File	Abstract of final technical reports

Sources: Agriculture, Defense, Energy, EPA, and NASA.

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Abbreviations

EPA	Environmental Protection Agency
FDP	Federal Demonstration Partnership
FOIA	Freedom of Information Act
NARA	National Archives and Records Administration
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NSF	National Science Foundation
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy

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United States General Accounting Office
Washington, D.C. 20548

November 14, 2003

The Honorable Richard C. Shelby
United States Senate

Dear Senator Shelby:

University research is a vital part of the nation's research and development efforts. Because there is broad consensus that university research is a long-term, national investment in the future, the federal government has been the primary source of funding for this research. In fiscal year 2001, federal agencies provided $19 billion, or about 60 percent of all funding for university research. Eight agencies—the Departments of Agriculture, Defense, Education, and Energy; the Environmental Protection Agency (EPA); the National Aeronautics and Space Administration (NASA); the National Institutes of Health (NIH), within the Department of Health and Human Services; and the National Science Foundation (NSF)—obligated 97 percent of the university research funding, with NIH and NSF alone accounting for $14.2 billion. The Office of Science and Technology Policy (OSTP) coordinates the development of standard practices among federal agencies through the National Science and Technology Council. For example, the Council is undertaking a review of policies, procedures, and plans relating to the business relationship between federal agencies and research performers with the goal of improving the performance and management of federally funded research.

Historically, the primary return on the federal government's investment in university research was the advancement of scientific knowledge. Science progresses through open communication among scientists and the sharing of research results. Publication of research results in peer-reviewed scientific journals is an academic tradition that both validates and disseminates these results.

More recently, the federal investment in university research not only has advanced scientific knowledge but also has yielded thousands of inventions each year that have fostered the development of new technologies, stimulated the creation of new jobs, and improved the quality of life. For some universities, it has also yielded new streams of income that helped to support their research and education missions. The Bayh-Dole Act of 1980 has facilitated commercialization of university technology by giving universities, among others, the right to own their federally funded inventions and license them to businesses. As the importance of university

research to technological innovation has increased, partnerships between universities and businesses have also grown, giving rise to concerns that financial conflicts of interest might restrict the dissemination of research results or bias the conduct or results of federally funded research.

Industry groups and others have also expressed concerns about the need, in certain instances, for access to the scientific data that underlie the published results of federally funded research. In response, in November 1999, the Congress enacted a provision, commonly called the Shelby Amendment, requiring the Director of the Office of Management and Budget (OMB) to amend Circular A-110 for universities, hospitals, and other nonprofit organizations. Under this amendment, federal agencies are directed to provide scientific data in response to a Freedom of Information Act (FOIA) request if the published results of federally funded research are used in developing a federal agency action that has the force and effect of law.

You requested that we examine federal agencies' actions to ensure that (1) the results of the university research grants they fund are made available to the public and (2) universities receiving such grants implement policies for identifying and managing possible financial conflicts of interest. In addition, as agreed with your office, appendix I provides information on agencies' actions in implementing the Shelby Amendment. Our review focused on the Departments of Agriculture, Defense,[1] Education, and Energy; EPA; NASA; NIH; and NSF. As part of our review, we conducted a Web-based survey of the 200 universities that received the most federal funding for research and development in fiscal year 2000. We received responses from 171 universities, an 86 percent response rate. The universities' aggregated responses are available at http://www.gao.gov/special.pubs/gao-04-223sp.

Results in Brief

Each of the eight federal agencies we examined relies on university scientists who receive federally funded research grants to make the results available to the public; five of these agencies also disseminate results by posting them on their Web sites. Although university scientists customarily

[1]Within Defense, we generalized the research grant terms and conditions of the Office of Naval Research and the Air Force Office of Scientific Research to the entire department. The Army does not have standard research grant terms and conditions because each of its awarding offices is responsible for its own unique terms and conditions.

seek to publish their research results in peer-reviewed journals, agencies cannot require such publication as a condition for funding because it is impossible to ensure in advance that the results will be deemed by peer review to be acceptable for publication. Agencies do, however, explicitly encourage funding recipients to make results available to the public, and they consider scientists' publication records in reviewing grant applications. Agriculture, Defense, Energy, EPA, and NASA also disseminate the results of the research they fund by posting researchers' final reports on their Web sites because, according to officials at these agencies, Web sites offer an effective way to share information among scientists, as well as with the public. In contrast, NIH officials told us that they do not post researchers' final reports because, in the biomedical field, the risks associated with posting results that have not been scrutinized and validated by peer review are too great. Similarly, NSF officials said that NSF does not post results, partly because some scientific journals reject manuscripts if the results have already been posted on the Web. Education currently is considering how best to respond to the directive in the Education Sciences Reform Act of 2002 to widely disseminate the findings and results of scientifically valid research in education. We are recommending that Education post the results of the research it has funded on its Web site to facilitate access to and maximize the benefits of its research investment. Education agreed with our recommendation.

NIH and NSF are the only federal agencies that require universities to implement policies for identifying and managing possible financial conflicts of interest for the research they fund; the other agencies do not have any standards to protect against financial conflicts of interest in university research. The NIH and NSF standards, promulgated in July 1995, place primary responsibility on universities to institute appropriate policies and procedures for identifying and managing potential conflicts of interest. Under these standards, a financial conflict of interest might be resolved by eliminating or reducing the conflict or it might be managed by establishing an oversight committee to monitor the conduct and the reporting of the research. The other six agencies do not have financial conflict of interest standards for universities, in part because some of the agencies believe that identifying and managing conflicts of interests is the responsibility of the universities. Of the 171 university respondents, 148 (87 percent) reported that all of their federally funded research is covered by financial conflict of interest policies that are consistent with NIH's and/or NSF's standards. However, 17 university respondents reported that they do not extend either the NIH nor the NSF financial conflicts of interest requirements to cover research grants funded by other federal agencies. Unless federal agencies

uniformly require that universities implement financial conflict of interest policies, the government cannot properly safeguard against conflicts of interest that might bias federally funded research. We are recommending that the National Science and Technology Council coordinate the development of uniform federal requirements for universities and other funding recipients to identify and resolve financial conflicts of interest that might bias the design, conduct, or reporting of federally funded research. OSTP officials agreed with the thrust of our recommendation that uniform federal requirements be developed to identify and resolve financial conflicts of interest. However, the OSTP officials noted that recent experience in developing a common rule for research misconduct has demonstrated that the process of reaching consensus among federal agencies can be difficult and prolonged.

Background

The Bayh-Dole Act of 1980 (Pub. L. No. 96-517, Dec. 12, 1980) has fostered linkages between universities and businesses by giving universities, other nonprofit organizations, and small businesses the option to retain title to the inventions they make in the course of federally funded research. Before 1980, federal agencies generally retained title rights to any inventions made in the course of the research they funded. Funding recipients seeking to commercialize such inventions often faced long delays and uncertainty when they asked the funding agencies to waive their rights. Since 1980, universities have upgraded and expanded their technology licensing efforts, particularly in such fields as biomedicine and computer technology. Federal agencies and industry also substantially increased their funding of university research—federal funding grew from $8 billion (in 2001 dollars) in fiscal year 1980 to $19.2 billion in fiscal year 2001, and industry funding grew from $461 million (in 2001 dollars) to $2.2 billion during this period. For the Association of University Technology Managers' survey for fiscal year 2001,[2] U.S. university respondents reported that they (1) executed 3,282 technology licenses and options, (2) received $852 million in gross license income, and (3) held equity in 348, or 70 percent, of the 494 start-up

[2]Beginning in 1993, the Association of University Technology Managers has annually surveyed U.S. and Canadian institutions on their patenting and licensing activities. The participants in the fiscal year 2001 survey were 142 U.S. universities, 28 U.S. hospitals and research institutes, 27 Canadian institutions, and 1 patent management firm.

companies that were formed around university-licensed technology.[3] (See app. II for information from our survey about universities' licensing activities with start-up companies.)

OMB Circular A-110 establishes uniform requirements for the administration of federal grants and cooperative agreements with institutions of higher education, hospitals, and other nonprofit organizations. For example, the circular requires that funding recipients submit performance reports to the funding agency at least annually, with a final technical report normally due within 90 days after the grant's termination or expiration. However, the circular provides flexibility by allowing the agencies to specify the content of these reports or to waive the final technical report. The National Science and Technology Council, established by Executive Order 12881 in November 1993, coordinates the development of governmentwide science and technology policies. For example, the Council's Subcommittee on Research Business Models is examining the effects of the changing nature of scientific research on business models for conducting federally funded research. In addition, 7 federal agencies, 84 research universities, and 6 other research institutions participate in the Federal Demonstration Partnership (FDP), which seeks to streamline the administrative processes for implementing OMB Circular A-110.[4]

In July 1995, the Department of Health and Human Services, which includes NIH, promulgated regulations on Objectivity in Research and NSF revised its Investigator Financial Disclosure Policy to establish consistent requirements for universities and most other grantees to identify and manage financial conflicts of interest.[5] Specifically, the NIH and NSF standards require that funding recipients implement policies for

[3]According to the Association of University Technology Managers, taking equity in a start-up company, partially in lieu of cash fees, is an important licensing approach because start-up companies rarely have a positive cash flow during their first years of operation and, therefore, need to conserve cash for investing in product development.

[4]FDP is an outgrowth of the Florida Demonstration Project formed in 1986. All of the federal agencies we reviewed, except Education, and 64 of our 171 university respondents participate in FDP and incorporate the FDP terms and conditions in their grant agreements.

[5]NIH funds almost all of the university research within Health and Human Services. The department also has promulgated regulations to protect human research subjects. (See 45 C.F.R. Part 46.)

(1) scientists to disclose any "significant financial interests"[6] to an official designated by the institution and (2) institutions to determine whether a real or apparent conflict exists and, if so, take appropriate actions to manage, mitigate, or eliminate the identified conflict. Under these regulations, a conflict of interest exists when the institution's designated official determines that a significant financial interest could directly and significantly affect the research design, conduct, or reporting. The financial benefit may result, for example, from an investigator owning stock in a company providing the research funding, or from an investigator having ownership interest in a company that may profit from a university invention. Conflicting interests are not necessarily unacceptable, and many can be managed through disclosure and oversight. The NIH regulation exceeds the scope of NSF's policy in some areas. For example, it requires that universities and other funding recipients report every identified possible conflict of interest, while NSF requires that institutions report only those conflicts that have not been resolved. (See app. III for a more detailed comparison of the NIH and NSF requirements.)

Federal Agencies Rely on University Scientists and Agency Web Sites to Disseminate Research Results

Federal agencies rely primarily on the university scientists who receive research grants to make their research results available to the public. Each agency encourages grantees to publish research results in the scientific literature, a practice that is steeped in academic tradition. Agriculture, Defense, Energy, EPA, and NASA also disseminate the results of the research they fund by posting scientists' final technical reports on their Web sites, and Education is considering whether to post research results. While NIH, NSF, and Education do not post research results on their Web sites, they post certain grant information, including abstracts submitted at the time of the award.

[6]Significant financial interests are defined, among other things, to include (1) the holdings of the investigator, the investigator's spouse, and any dependent children that exceed a $10,000 equity interest or a 5-percent ownership interest in a single entity and (2) salary, royalties, or other payments for the investigator and the investigator's spouse and dependent children that exceed $10,000 over the next 12-month period.

Agencies Rely on and Encourage Grant Recipients to Make Research Results Available

The eight agencies we examined rely on university scientists to disseminate the results of the research they fund, and their policies explicitly encourage principal investigators and universities to disseminate those results through presentations at scientific conferences and publishing in scientific journals. (See table 1.) Similarly, FDP's model terms and conditions for research grants state, "The recipient is expected to publish or otherwise make publicly available the results of the work conducted under the award." Publishing federally funded research results also is vital to university scientists because research publications are key to obtaining future grant awards, gaining professional recognition, and achieving tenure.

Table 1: Federal Agencies' Policies on Disseminating Research Results

Agency	Policy	Citation
Agriculture	The principal investigator is expected to publish or otherwise make publicly available the results of the work conducted under this award.	Cooperative State Research, Education, and Extension Service General Terms and Conditions
Defense	Publication of results of the research project in appropriate professional journal is encouraged as an important method of recording and reporting scientific information.	Office of Naval Research Research Terms and Conditions
	The recipient is expected to publish or otherwise make publicly available the results of the work conducted under this agreement.	Air Force Office of Scientific Research Grant Terms and Conditions
Education	Grantees are encouraged to publish the results of the work conducted under this award.	Individual grant agreements[a]
Energy	Recipients are encouraged to disseminate results promptly to the scientific community.	Office of Science, Grant Application Guide Reporting Requirements
EPA	EPA encourages the independent publication of the results of its extramural research in appropriate scientific journals.	National Center for Environmental Research Terms and Conditions
NASA	NASA requires prompt public disclosure of the results of its sponsored research and, therefore, expects significant findings from supported research to be promptly submitted for peer reviewed publication.	Guidebook for Proposers Responding to a NASA Research Announcement
NIH	[P]rincipal investigators and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. Starting with the October 1, 2003, receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.	NIH Grants Policy Statement and Final NIH Research Tools Policy (Dec. 23, 1999) Final NIH Statement on Sharing Research Data (Feb. 26, 2003)
NSF	Investigators are expected to promptly prepare and submit for publication ... all significant findings from work conducted under NSF grants. Investigators are expected to share with other researchers ... materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing.	NSF Grants Policy Manual

Sources: Agriculture, Defense, Education, Energy, EPA, NASA, NIH, and NSF.

[a]Education currently is revising its research dissemination policies in response to the Education Sciences Reform Act of 2002.

Agencies also indirectly encourage the dissemination of research results through their grant award practices. Officials at each agency said that peer review panels consider the publication record of the applicant (usually the principal investigator) in assessing the grant proposal. NSF, for example, requires that principal investigators requesting grant renewals include a list of publications generated with NSF's prior support. Agriculture officials told us that they are less likely to recommend renewal applications for continued funding if the funded project's results have not been published. Publications indicate to the agencies that the principal investigator has

made progress in his/her research and that the results are available to other scientists in the field. However, a research project may not generate publishable results because leading scientific journals require that manuscripts be reviewed by other experts in the field to validate the research findings prior to publication. The scientific journal may reject a manuscript because, for example, the reviewers conclude that the work adds little value to the field of study, the results are inadequately supported, or the research failed.

All but five of the university respondents reported that they have a policy or standard operating procedure that addresses whether sponsors are allowed to delay the publication of research results under certain circumstances, such as reviewing a manuscript for possible proprietary information or for intellectual property. Three universities—the California Institute of Technology, Howard University, and Iowa State University—reported that they do not permit any publication delays, while 160 universities allow a sponsor to review a manuscript prior to publication—typically from 30 to 90 days.[7] However, 10 universities allow a longer period of up to either 120 days or 180 days, and 1 university allows up to 365 days for the sponsor to review a manuscript for proprietary information.

Generally, research sponsors appear to adhere to the universities' time frames for reviewing manuscripts. Administrators reported the following:

- Fourteen universities were aware of one or more cases during the past 3 years of a sponsor delaying the publication of unclassified and nonsensitive research beyond the university's time limits.

- Three universities were aware of one or more cases during the past 3 years of a federal sponsor delaying the publication of research involving sensitive, but not classified, information beyond the university's time limits.

- Thirteen universities were aware of one or more cases during the past 3 years of a federal sponsor blocking, or attempting to block, publication of research involving sensitive, but not classified, information.

[7]According to NIH, a 30- to 60-day delay to secure intellectual property rights is generally viewed as reasonable. See "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts," (59 fr 55674).

However, several university administrators noted during the pretest of our survey instrument that publication delays can occur without the university's knowledge if the sponsor and the research team reach an accommodation without notifying university administrators.

Five Agencies Disseminate Research Results on Their Web Sites

As shown in table 2, Agriculture, Defense, Energy, EPA, and NASA use their Web sites to post research results, in some form, for grants that they issue.[8] For example, EPA posts summaries of annual and final technical reports on its National Center for Environmental Research Web site. These summaries include research accomplishments or findings, the reporting date, EPA agreement number, title, investigators, institution, research category, project period, objective of research, progress summary, conclusions (if applicable), publications/presentations, future activities, supplemental keywords, and other relevant Web sites. EPA's Web site also allows users to search for publications associated with a particular grant. NASA primarily posts abstracts of final technical reports on its Web site, although NASA plans to post mainly full technical reports in 2004.

Table 2: Agencies That Post Research Results on Their Web Sites

Agency	Web-based information system	Information posted
Agriculture	Current Research Information System	Annual and final technical reports
Defense	Defense Technical Information Center	Final technical reports
Energy	Information Bridge	Final technical reports
EPA	National Center For Environmental Research	Annual and final report summaries
NASA	Scientific and Technical Aerospace Reports File	Abstract of final technical reports

Sources: Agriculture, Defense, Energy, EPA, and NASA.

Note: Some agencies use their Intranet sites to provide greater access to research results for organizations with which they have a business relationship. For example, Defense's Scientific and Technical Information Network uses a customer registration and information release process to provide access to eligible contractors, academic institutions, and certain other federal agencies.

[8]The organic statutes for Energy and NASA call for them to widely disseminate the results of research that they fund.

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While Education, NIH, and NSF do not post research results on their Web sites, they post a project abstract written at the time of award stating how the research will be conducted and what researchers hope to accomplish. In November 2002, the Education Sciences Reform Act of 2002 (Pub. L. No. 107-279) established the Institute of Education Sciences and directed it to widely disseminate the findings and results of scientifically valid research in education. An Education official told us that after the members of the Institute's National Board of Educational Sciences have been appointed and confirmed, Education will consider how best to fulfill this requirement, particularly for the results of Institute-funded research that have not been peer reviewed. The official noted that the Institute's National Center for Education Evaluation currently disseminates the results of research performed under contract either through research publications or through its Web site after the results have been peer reviewed.

In addition to using their own Web sites, several agencies participate in collaborative Web-based efforts to share information, including research results. For example, Energy's Office of Scientific and Technical Information maintains Federal R&D Project Summaries, a Web-based portal to summary and award information for Energy, NIH, and NSF research grants. The office also maintains GrayLIT Network, a portal to full-text reports located on the Energy, Defense, EPA, and NASA information systems. In addition, an interagency working group from 11 major science agencies recently initiated the science.gov Web site, which provides a gateway to federal research and development results and other scientific information.

Officials at the eight agencies identified both advantages and disadvantages to posting all funded research results on agencies' Web sites. Most of the agency officials told us that posting technical reports on agencies' Web sites is an effective way to share information among scientists in the field of research, as well as with the public. In explaining why they have chosen not to post all results on their Web site, NIH and NSF officials cited concerns that grant results posted prior to peer review and publication may be incomplete or incorrect and could mislead other researchers or the public. According to NIH officials, the risk associated with posting results that have not been scrutinized and validated by peer review is simply too great in the biomedical field. In addition, NSF officials were concerned that a scientific journal would reject a manuscript because it views reports posted on the Web as publications. Some agency officials also expressed concern that a final technical report might be posted before the university

files a patent application for an invention, thereby preventing it from obtaining a patent.

Among the 171 university respondents to our survey, 91 universities (53 percent) supported posting the grantee's final technical reports on the agency's Web site, and 31 universities (18 percent) opposed posting the final technical report, while 49 universities (29 percent) either were uncertain or did not respond. Primary advantages that universities cited for posting final technical reports on an agency's Web site include facilitating the access of other scientists to research results, facilitating collaboration among scientists, providing prompt dissemination of research results, and providing a public record if the results of a research project are not published. Primary disadvantages that universities cited for posting final technical reports are the potential for (1) an invention to be prematurely disclosed, (2) a scientific journal to reject a manuscript because it views posted reports as publications, (3) proprietary information to be disclosed, (4) research results to be prematurely disclosed, (5) incomplete or misleading report results to be prematurely disseminated, (6) an investigator to be to harassed by opponents to the research, and (7) universities to incur added administrative costs in complying with agency requirements.

Only NIH and NSF Require Financial Conflict of Interest Standards for Grant Recipients

NIH and NSF, the two largest federal supporters of university research, are the only federal agencies we examined that have adopted standards intended to protect against financial conflicts of interest among university grantees. The other six agencies do not require universities and other grantees to identify and manage possible financial conflicts of interest involving their research. According to officials from these agencies, it is the universities' responsibility to protect against conflicts of interest in university research. While 87 percent of our survey respondents reported that all of their federally funded research is covered by financial conflict of interest policies that are consistent with either NIH's or NSF's standards, 17 universities—including 5 universities in the University of California system—reported that they do not extend either the NIH or the NSF financial conflicts of interest requirements to cover research grants funded by other federal agencies.

Agencies without Financial Conflict of Interest Standards Believe Universities Should Take the Lead in Implementing Policies

While both NIH and NSF promulgated regulations in 1995 that require universities to implement financial conflict of interest policies, the other six federal agencies do not require that their grantees have similar standards. According to Agriculture and Energy officials, universities should take responsibility for developing and implementing policies for identifying and managing financial conflicts of interest involving their scientists. Defense and NASA officials told us that they have not experienced enough problems to justify adopting financial conflict of interest standards for universities and other grantees. These officials added that the potential for financial conflicts of interest in the scientific fields that they fund is generally lower than in the biomedical field. However, NSF supports research in many of the same fields of research as these agencies.

Most Universities Report That Their Financial Conflict of Interest Policies Are Consistent with NIH and/or NSF Standards

All of the 171 university respondents to our survey reported that they had one or more policies for addressing possible financial conflicts of interest by research investigators. Of the respondents, 148 universities (87 percent) reported having financial conflict of interest policies consistent with either NIH's or NSF's regulations that apply to all federally funded research. More specifically, 135 universities (79 percent) reported that they have a single conflict of interest policy that applies to all of their research. These universities' policies are consistent with one of the 10 guidelines that the Association of American Universities' Task Force on Research Accountability proposed for managing individual conflicts of interest: "Treat research consistently, regardless of funding source—all research projects at an institution, whether federally funded, funded by a non-federal entity, or funded by the institution itself, should be managed by the same conflict of interest process and treated the same."[9]

In contrast, 17 universities reported that some of the federally funded research they perform is not covered by financial conflict of interest policies that are consistent with either NIH's or NSF's regulations. For example, 5 universities in the University of California system reported that their financial conflict of interest policies apply to research funded by NIH

[9]Association of American Universities, Task Force on Research Accountability: *Report on Individual and Institutional Financial Conflict of Interest*, October 2001. In asserting that universities are accountable for the research they perform, the task force provided 10 guidelines for managing individual conflicts of interest and recommended a three-step approach for addressing institutional conflicts of interest.

or NSF, but not to research funded by other federal agencies.[10] The Massachusetts Institute of Technology and Yale University reported that they have specific policies that cover research funded by NIH and NSF, while their institutional policies cover all other funded research. Six other universities did not provide a response.

Overall, 124 universities strongly supported, and 25 universities somewhat supported, creating a single financial conflict of interest policy for all federally funded research. Among the other respondents, 19 universities either did not have a strong opinion or did not respond to the question, while only 3 universities either strongly or somewhat opposed a single financial conflict of interest policy for all federally funded research. The university respondents did not agree, however, on which agency's standards should serve as the basis for a single federal policy: among the 133 universities that expressed an opinion, 72 preferred the NIH regulation, 56 preferred the NSF regulation, while 5 stated that either would be acceptable.

To implement their financial conflict of interest policies, 140 of the 171 universities (82 percent) reported that they require scientists to indicate whether or not a conflict may exist when a grant proposal is submitted; 108 universities (63 percent) require scientists to annually submit financial disclosure forms to appropriate institution officials; and 139 universities (81 percent) require scientists to update financial disclosure forms during the year if new possible financial conflicts of interest are identified. A policy that incorporates all three of these requirements is consistent with the Association of American Universities' Task Force on Research Accountability guideline: "Disclose financial information to the institution—individuals engaged in research should disclose on an annual basis all financial interests related to university research, and provide updated information when new financial circumstances may pose a conflict of interest and when grant applications are submitted." All but 6 of the 171 universities reported that they require at least one of these three types of financial disclosure.

[10]Universities in the University of California system also must comply with state requirements under the Political Reform Act of 1974. The act established a lower income and equity threshold than the NSF and NIH regulations for disclosing financial interests, but the relationship between the university scientist and an affected company is more tightly limited to only those companies directly supporting the research through gifts, grants, or contracts.

In addition, 56 universities reported that their policy requires that the federal funding agency be notified whenever a financial conflict of interest is identified. In comparison, 62 universities reported that their policies require that only certain federal funding agencies be notified, 49 universities do not have a policy for notifying federal funding agencies about identified financial conflicts of interest, and 4 universities did not respond about their notification policies.

Our survey results indicate that several universities have tightened their policies for financial conflicts of interest in recent years to comply with the NIH and NSF requirements. Specifically, all of our 171 respondents reported that they have financial conflict of interest policies, while a survey reported in the November 2000 issue of the *New England Journal of Medicine* found that 15 of the 250 institutional respondents (6 percent) did not have a policy on conflicts of interest.[11] In response to the November 2000 survey, NIH reviewed the financial conflict of interest policies of a representative sample of more than 100 universities and other institutions. NIH found that, generally, the institutions had developed policies that reflected a serious desire to inform and assist their investigators in complying with NIH's regulation. However, NIH found several specific areas of noncompliance and identified four major areas of concern that the institutions' financial conflicts of interest policies need to address: (1) many policies are not separated from other institutional policies through a distinct part, appendix, or document; (2) investigators face an increased burden because the many policies do not provide electronic links to supporting information; (3) many policies are confusing because their applicability and terminology are unclear; and (4) many policies include numerous examples of vague language or statements.

Upon review of our university survey results, officials at Agriculture, Energy, EPA, and NASA told us that OMB should take the lead in developing a uniform, governmentwide requirement for addressing possible financial conflicts of interest that is consistent with NIH's and NSF's standards. NIH and NSF officials also supported developing a uniform requirement that is consistent with their standards. Defense officials said they were ready to work with other federal agencies on

[11]S. Van McCrary et al., "A National Survey of Policies on Disclosure of Conflicts on Interest in Biomedical Research," *The New England Journal of Medicine* 343, No. 22 (2000): 1621-1626. The authors surveyed 297 medical schools and other research institutions that received more than $5 million in total grants annually from NIH or NSF to analyze their policies on conflicts on interest.

governmentwide regulations, if regulations are warranted. OMB and OSTP officials believe that the National Science and Technology Council, which OSTP coordinates, is in the best position to develop a uniform financial conflict of interest standard for federally funded research.

Conclusions

A fundamental principle of scientific research is that wide dissemination of research results is vital for validating these results and advancing the field of science. Posting final research reports, or similar information, on federal agencies' Web sites can advance scientific research by providing other scientists with timely access to research results and facilitating collaboration. Posting this information also provides access to members of the public interested in the research and a public record if the results of agency-funded research are not published, thus maximizing the benefit of the federal investment. For these reasons, five federal agencies, including Energy and NASA, already routinely disseminate research results through their Web sites. While posting research results might create concerns in some fields, such as biomedical research, these concerns are less applicable for Education, which like Energy and NASA, has a specific statutory requirement to widely disseminate research results.

The growing relationship between universities and businesses since passage of the Bayh-Dole Act has led to an increase in possible financial conflicts of interest, as businesses have increased their funding of university research and some universities have collected more than $10 million in royalties in a given year for technologies they have developed. In response to the NIH and NSF requirements, all of the universities we surveyed have implemented policies for identifying and managing possible conflicts of interest. However, some universities have not extended their policies to cover research funded by other agencies, which also provide substantial amounts of research funding, and OMB Circular A-110 does not address financial conflicts of interest. Unless all federal agencies require that universities have appropriate conflict of interest policies, the government cannot ensure that safeguards are in place to protect the integrity of scientific research, and the public's investment.

Recommendations for Executive Action

To better ensure that the findings and results of scientifically valid research in education are widely disseminated, we recommend that the Secretary of Education direct the new Institute of Education Sciences to post the final technical reports of the research it funds on its Web site.

To safeguard against bias in the design, conduct, or reporting of federally funded research, we recommend that the National Science and Technology Council coordinate the development of uniform federal requirements for universities and other funding recipients to identify and resolve financial conflicts of interest. The NIH and NSF standards provide a useful starting point for this requirement.

Agency Comments and Our Evaluation

We provided Education, OSTP, Agriculture, Defense, Energy, EPA, NASA, NIH, and NSF with a draft of this report for their review and comment. Education agreed with our recommendation to post the results of the research it has funded on its Web site, stating that the department is currently exploring how to best implement the Education Sciences Reform Act's provisions while not discouraging grantees from having their work published in scientific journals. (See appendix IV for Education's written comments.) We met with OSTP officials, including the Associate Director for Science, who agreed with the thrust of our recommendation that the National Science and Technology Council coordinate the development of uniform federal requirements to identify and resolve financial conflicts of interest. However, the OSTP officials noted that recent experience in developing a common rule for research misconduct has demonstrated that the process for reaching consensus among federal agencies can be difficult and prolonged. We continue to believe that federal agencies should develop a single, uniform requirement for financial conflicts of interest. Through their experiences in implementing standards since 1995, NIH and NSF can provide important insights into the benefits and costs of alternative approaches in areas where their requirements differ.

The Deputy Administrator for Extramural Programs within Agriculture's Cooperative State Research, Education, and Extension Service stated, in oral comments, that the Service agreed with our recommendation and will, where appropriate, implement financial conflict of interest standards similar to those of NIH and NSF. Defense, Energy, EPA, NASA, NIH, and NSF agreed with the factual presentation of the report. (See app. V for NASA's written comments, and app. VI for NIH's written comments.) Several agencies also provided specific comments to improve the report's technical accuracy, which we incorporated as appropriate.

Scope and Methodology

To assess the actions that federal agencies have taken to ensure the public's access to authoritative and unbiased scientific research at universities, we examined the policies and procedures of the eight federal agencies that primarily fund university research—Agriculture, Defense, Education, Energy, EPA, NASA, NIH, and NSF. Specifically, we performed the following audit steps:

- To assess agencies' actions to ensure that the results of the university research they fund are made available to the public, we reviewed each agency's policies and procedures for disseminating research results and interviewed agency officials. We also accessed the final technical reports for several university grant projects from the Web sites of the five agencies that post research results.

- To assess agencies' actions to ensure that universities implement policies for identifying and managing possible financial conflicts of interest, we examined whether each agency has regulations or policies requiring that universities identify and manage possible financial conflicts of interest. We also interviewed cognizant officials about their procedures for ensuring that universities are implementing financial conflict of interest policies. We did not examine the extent to which agencies have taken additional actions to protect against financial conflicts of interest for research involving human subjects, a topic examined in a November 2001 GAO report.[12]

- To assess agencies' actions to implement the Shelby Amendment, we examined the 1999 legislation; OMB's revisions to Circular A-110; and the actions each agency has taken to implement the circular's revisions. We also discussed these actions with cognizant agency officials, asked them whether they had received any FOIA requests that cited the Shelby Amendment, and, if so, asked them to provide information about each such request. We then reviewed the agency's disposition of these FOIA requests.

In addition to our review of federal agencies' actions, we conducted a Web-based survey of the 200 universities and colleges that received the most federal research funding in fiscal year 2000. The survey contained 42

[12]See U.S. General Accounting Office, *Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest*, GAO-02-89 (Washington, D.C.: Nov. 26, 2001).

questions that asked about (1) their policies and procedures for ensuring that federally funded research results are made available to the public, (2) their views of the advantages and disadvantages of posting a grant's final technical report to the agency's Web site, (3) their conflict of interest and financial disclosure policies, (4) any FOIA requests federal agencies had received that asked for access to research data, and (5) data on their research funding and technology transfer activities.

We pretested the content and format of the questionnaire with research office administrators at the Georgia Institute of Technology, Emory University, Washington University, the University of Missouri, the University of Colorado, the Colorado School of Mines, George Washington University, and the University of Maryland. During the pretest, we asked the administrators to determine whether the survey questions were clear, the terms used were precise, and the questions were unbiased. We also assessed the usability of the Web-based format. We made changes to the content and format of the final questionnaire based on pretest results.

We received responses from 171 of the 200 universities surveyed, for a response rate of 86 percent. Respondents included 44 of the 50 universities that received the most federal funding in fiscal year 2000. We performed analyses to identify inconsistencies in the data and resolved them. The universities' aggregated responses are available at http://www.gao.gov/special.pubs/gao-04-223sp.

We conducted our review from August 2002 through September 2003 in accordance with generally accepted government auditing standards.

We are sending copies of this report to the appropriate House and Senate Committees, the Director of OSTP, the Secretary of Agriculture, the Secretary of Defense, the Secretary of Education, the Secretary of Energy, the Administrator of EPA, the Administrator of NASA, the Director of NIH, the Director of NSF, and the Director of OMB. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about the report, please contact me at (202) 512-3841. Key contributors to this report were Richard Cheston, Vondalee Hunt, Ulana Bihun, Donald Pless, and Lynn Musser.

Sincerely yours,

Robin M Nazzaro

Robin Nazzaro
Director, Natural Resources
and Environment

Agencies' Actions in Implementing the Shelby Amendment

The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, (Pub. L. No. 105-277) required the Director of the Office of Management and Budget (OMB) to amend Circular A-110 by incorporating a provision known as the Shelby Amendment.[1] Among other things, the Shelby Amendment requires that (1) federal awarding agencies ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act (FOIA) and (2) if the agency obtaining the data does so solely at the request of a private party, the agency may charge a reasonable user fee equaling the incremental cost of obtaining the data. The Shelby Amendment grew out of a controversy that arose over the Environmental Protection Agency's (EPA) proposal to tighten Clean Air Act standards for small airborne particulates in 1997. EPA's proposed rule cited the published results of a 30-year epidemiological study funded by the National Institutes of Health (NIH) and conducted by Harvard University. Various industry groups that opposed EPA's proposed regulation asked to review original data of the study. However, Harvard denied the requests, citing both confidentiality agreements with human subjects and the volume of data accumulated.

On November 6, 1999, OMB published revisions to Circular A-110 in the *Federal Register* in response to the Shelby Amendment. Under the revision, a subject institution must provide the research data to the funding agency in response to a FOIA request if a federal agency has used the published research findings in developing an agency action that has the force and effect of law. In March 2000, 15 federal agencies published an interim final rule in the *Federal Register* that codified the OMB Circular A-110 revision. These agencies included Agriculture, Defense, Energy, Education, EPA, the National Aeronautics and Space Administration (NASA), and NIH. National Science Foundation (NSF) officials told us that NSF incorporated the revision by reference to OMB Circular A-110 in its grant agreements.

Only NIH and EPA have received FOIA requests citing the Shelby Amendment. In reviewing the requests, both agencies determined that the requests did not meet the OMB Circular A-110 criteria. (See table 3.) Of the 40 requests received by NIH, 20 requested copies of either funded grant applications or contract records, not research data; 9 requested data generated from grants funded prior to the effective date of the NIH

[1]OMB Circular A-110 establishes uniform administrative requirements for grants and agreements with institutions of higher education, hospitals, and other nonprofit organizations.

regulation implementing the Shelby Amendment; and 4 were withdrawn. NIH officials told us that NIH determined that the remaining seven requests were not applicable to the Shelby Amendment; however, information on the basis for this decision was unavailable because NIH had destroyed the FOIA files 2 years after its final response, in accordance with the National Archives and Records Administration's (NARA) records retention schedule. EPA denied both requests it received because the requested data were generated by projects funded prior to the effective date of its regulation implementing the revision to OMB Circular A-110.

Table 3: NIH's and EPA's Disposition of FOIA Requests Citing the Shelby Amendment, as of August 31, 2003

Request	Request date	Response date	Agency disposition
NIH			
1	Nov. 4, 1999	Apr. 29, 2002	Request was withdrawn
2	Nov. 5, 1999	Pending	Not applicable because the projects for which data are sought were funded before the effective date (April 2000)
3	Jan. 20, 2000	July 3, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
4	Feb. 1, 2000	June 9, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
5	Feb. 1, 2000	July 18, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
6	Feb. 1, 2000	Apr. 17, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
7	Feb. 29, 2000	Aug. 2, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
8	Mar. 31, 2000	Mar. 31, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
9	May 16,2000	June 23, 2000	Request was withdrawn
10	June 28, 2000	July 6, 2000	Not applicable. Information on the basis for NIH's decision is unavailable because the FOIA file had been destroyed in accordance with NARA's records retention schedule
11	Aug. 4, 2000	Dec. 14, 2000	Request did not identify the grants for which data were sought; However, given the date of publications cited, the projects were funded before April 2000, the effective date of the NIH regulation

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Request	Request date	Response date	Agency disposition
12	Dec. 20, 2000	Dec. 26, 2000	Not applicable because the grants for which data were sought were funded before April 2000, the effective date of the NIH regulation
13	Jan. 19, 2001	Feb. 28, 2001	Not applicable because requester sought only a copy of the funded grant application, not data
14	Aug. 27, 2001	Nov. 15, 2001	Not applicable because requester sought only a copy of the funded grant application, not data
15	Oct. 16, 2001	May 30, 2002	Not applicable because the grants for which data were sought were funded before April 2000, the effective date of the NIH regulation
16	Oct. 16, 2001	Pending	Not applicable because the projects for which data are sought were funded before April 2000, the effective date of the NIH regulation
17	Jan. 14, 2002	Feb. 11, 2002	Not applicable because requester sought only a copy of the funded grant application, not data
18	Mar. 20, 2002	Apr. 18, 2002	Not applicable because requester sought only a copy of the funded grant application, not data
19	Apr. 1, 2002	June 14, 2002	Not applicable because the grants for which data were sought were funded before April 2000, the effective date of the NIH regulation
20	June 17, 2002	July 18, 2002	The study referenced in the request could not be identified. In addition, according to information provided by the requester, if the study existed, it predated the effective date of the NIH regulation
21	June 24, 2002	Pending	Not applicable because requester sought only copies of funded grant applications, not data
22	June 24, 2002	July 22,2002	Not applicable because requester sought only a copy of the funded grant application, not data
23	July 2, 2002	Pending	Not applicable because requester sought only a copy of the funded grant application, not data
24	July 25, 2002	Aug. 21, 2002	Not applicable because requester sought only a copy of the funded grant application, not data
25	Aug. 29, 2002	Pending	Not applicable because requester sought only a copy of the funded grant application, not data
26	Sept. 27, 2002	Oct. 2, 2002	Not applicable because requester sought only copies of funded grant applications, not data
27	Oct. 3, 2001	Nov. 7, 2002	Not applicable because requester sought only copies of funded grant applications, not data
28	Oct. 28, 2002	Feb. 6, 2003	Not applicable because the grant for which data were sought was funded before April 2000, the effective date of the NIH regulation
29	Dec. 12, 2002	Sept. 15, 2003	Not applicable because requester sought only copies of funded grant applications, not data
30	Jan. 9, 2003	July 21, 2003	Request was withdrawn
31	Feb. 3, 2003	Feb. 20, 2003	Not applicable because requester sought only a copy of contract records, not data
32	June 23, 2003	Aug. 18, 2003	Not applicable because requester sought only a copy of a funded grant application, not data

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Request	Request date	Response date	Agency disposition
33	June 27, 2003	Sept. 26, 2003	Not applicable because requester sought only a copy of a funded grant application, not data
34	July 28, 2003	Not applicable	Request was withdrawn
35	July 28, 2003	Aug. 28, 2003	Not applicable because requester sought only copies of funded grant applications, not data
36	July 28, 2003	Pending	Not applicable because requester sought only copies of funded grant applications, not data
37	Aug. 1, 2003	Sept. 5, 2003	Not applicable because requester sought only a copy of a funded grant application, not data
38	Aug. 1, 2003	Pending	Not applicable because requester sought only a copy of a funded grant application, not data
39	Aug. 10, 2003	Pending	Not applicable because requester sought only a copy of a funded grant application, not data
40	Aug. 19, 2003	Sept. 3, 2003	Not applicable because the grants for which data were sought were funded before April 2000, the effective date of the NIH regulation
EPA			
1	Dec. 9, 1999	April 24, 2001	Not applicable because the projects for which data were sought were funded before the effective date
2	Dec. 9, 1999	April 24, 2001	Not applicable because the projects for which data were sought were funded before the effective date

Sources: NIH and EPA.

More recently, OMB published a proposed bulletin and guidelines to ensure that agencies conduct peer reviews of the most important scientific and technical information relevant to regulatory policies that they disseminate to the public, and that the peer reviews are reliable, independent, and transparent.[2] The guidance would supplement the requirements that many agencies have for peer review of "significant regulatory information," which is scientific or technical information that qualifies as "influential" under OMB's information quality guidelines and is relevant to regulatory policies.[3] Specifically, the proposed guidelines state that, to the extent permitted by law, an agency shall have an appropriate and scientifically–rigorous peer review conducted on all significant regulatory information

[2]OMB published a notice in the *Federal Register* on September 15, 2003, announcing a proposed OMB bulletin under Executive Order No. 12866 and supplemental information quality guidelines.

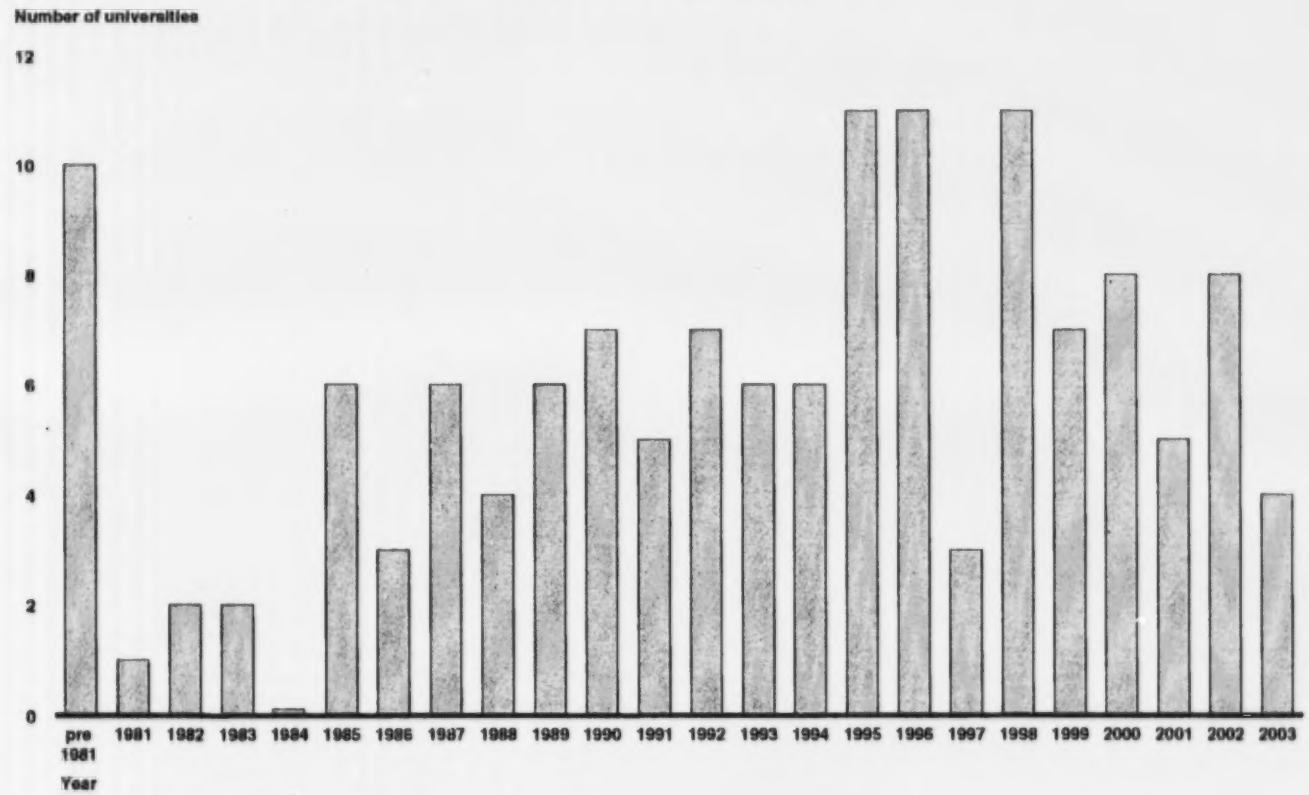
[3]The proposed guidelines define significant regulatory information to exclude most routine statistical and financial information; studies that have already been adequately peer-reviewed; and science that is not directed toward regulatory issues, such as most of the scientific research conducted by NIH and NSF.

that the agency intends to disseminate. In addition, the proposed guidelines state that, to the extent permitted by law, an agency shall have formal, independent, external peer review conducted for so-called "especially significant regulatory information" which would apply to significant regulatory information if (1) the agency intends to disseminate the information in support of a major regulatory action, (2) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than $100 million in any year, or (3) the Administrator of the Office of Information and Regulatory Affairs determines that the information is of significant interagency interest or is relevant to an administration policy priority.

Universities' Acceptance of Equity in Start-up Companies

Among the 171 respondents to our survey, 155 universities reported that they, or their affiliates, have the option to accept equity as a means of payment for licensed technology. As shown in figure 1, since the enactment of the Bayh-Dole Act in December 1980, these universities have increasingly begun receiving equity in start-up companies in lieu of receiving license fees and royalties. Prior to the act, only 10 universities accepted equity in start-up companies.

Figure 1: The Year Universities First Received Equity in a Start-up Company



Source: GAO survey of universities.

As of March 2003, 123 universities reported that they held equity in at least one start-up company, and 44 of these universities reported that they held

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equity in at least 10 start-up companies. The Massachusetts Institute of Technology held equity in 116 start-up companies at that time. Furthermore, 93 universities reported that they held, on average, less than 10 percent of the start-up companies' equity, and 31 universities reported that they held, on average, 10 percent or more of the start-up companies' equity. While 16 universities limit equity ownership to at most 10 percent, 116 universities reported that their institutional policy does not restrict the percentage of equity ownership they can hold in a start-up company.

Comparison of NIH's and NSF's Financial Conflict of Interest Standards

On July 11, 1995, the Department of Health and Human Services, which includes NIH, promulgated regulations and NSF revised its Investigator Financial Disclosure Policy to establish consistent requirements for universities and other grantees, with certain exceptions, to identify and manage real or apparent financial conflicts of interest. The stated purpose of these requirements is to ensure a reasonable expectation that the design, conduct, and reporting of research will be unbiased by any conflicting financial interest of the investigator. The effective date of these standards was October 1, 1995.

Both NIH and NSF define a "significant financial interest" as anything of monetary value with the following exceptions:

- salaries, royalties, and remuneration from the applicant institution;
- any ownership interest in the institution, if the institution is an applicant under the Small Business Innovation Research program;
- income from seminars, lectures, teaching engagements, and service on advisory committees or review panels;
- an equity interest that—when aggregated for the investigator, spouse, and dependent children—does not exceed $10,000 and does not represent more than 5 percent ownership interest in a single entity; or
- salary, royalties, or other payments that—when aggregated for the investigator, spouse and dependent children—do not exceed $10,000 over the next 12 months.

The NIH regulations (42 C.F.R. Part 50 and 45 C.F.R. Part 94) require that each institution, except Phase I applicants for the Small Business Innovation Research program, takes the following actions:

- Maintains a written, enforced policy on conflict of interest complying with the regulations, and inform investigators of the policy. The institution must take reasonable steps to ensure that subgrantees comply with its policy.
- Designates an institutional official who will review financial disclosure statements.

- Requires that each investigator submit to the institutional official, by the time the application is submitted for funding, a listing of significant financial interests that would reasonably be affected by the research.[1]

- Provides guidelines for designated officials to identify conflicts of interest and take necessary action to manage, reduce, or eliminate those conflicts. Under the regulations, a conflict of interest exists when the designated official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the funded research.

- Maintains records for 3 years after the date of the submission of the final report of expenditures.

- Establishes adequate enforcement mechanisms and provide for appropriate sanctions.

- Certifies in each application for funding that the institution has an administrative process to manage conflicts of interest and that, prior to any expenditure of funds, the institution will report the existence of a conflict and assure that it is being managed, reduced, or eliminated.

If an investigator fails to comply with the institution's policies and has, thereby, biased the research, the institution must report the noncompliance immediately to NIH and inform NIH of the action that has been, or will be, taken. If this failure occurs in a project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the institution must require that it be disclosed in each public presentation of the results of the research.

NSF's policies were developed in close conjunction with the NIH regulations but differ in the following significant respects:

- NSF has no conflict of interest requirement governing subgrantees.

- NSF exempts all entities with less than 50 employees from its standard.

[1]The investigator is the principal investigator and any other person responsible for the design, conduct, or reporting of research funded by NIH. For financial interest purposes, the term also includes the investigator's spouse and dependent children.

- NSF requires that records be retained for 3 years after the termination of the award instead of 3 years after the last financial statement has been submitted.

- NSF requires that the institution provide notification of a conflict of interest only if the institution is unable to resolve the conflict.

- NSF permits research to proceed, in spite of disclosed conflicts, if the review determines that restrictions would be ineffective or that the benefits of proceeding outweigh the consequences of any negative impact. NIH does not address this issue in its policy.

Comments from the Department of Education

UNITED STATES DEPARTMENT OF EDUCATION
INSTITUTE OF EDUCATION SCIENCES

THE DIRECTOR

OCT 31 2003

Mr. Richard Cheston
Assistant Director, Natural Resources
and Environment
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Cheston:

Thank you for the opportunity to review and comment on your draft report entitled *University Research: Federal Agencies Need to Better Protect against Financial Conflicts of Interest* (GAO-04-31).

The GAO recommends that the Secretary of Education direct the Institute of Education Sciences (the Institute) to post the final technical reports of the research the Institute funds on the Institute's Web site. The Education Sciences Reform Act (ESRA) provides that all research, statistics and evaluation reports conducted by, or supported through, the Institute must undergo rigorous peer review before the Institute can publish them or otherwise make them available to the public. See Pub. L. 107-279, section 186(c).

Consistent with this provision, the Institute intends to post on its web site final reports generated by contractors after the reports have gone through peer review. As for reports generated under a grant or cooperative agreement, section 134 (b)(1) of the ESRA states that the Director shall establish a peer review process for evaluating and assessing the products of research from grant and cooperative agreement recipients. The Institute is currently exploring how to best implement this provision while not discouraging grantees from having their work published in scientific journals.

Any questions about this response should be directed to Dr. Lynn Okagaki at 202-219-2006 or lynn.okagaki@ed.gov.

Sincerely,

Grover J. Whitehurst

555 NEW JERSEY AVE., NW WASHINGTON, DC 20208

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Comments from the National Aeronautics and Space Administration

National Aeronautics and
Space Administration
Office of the Administrator
Washington, DC 20546-0001

October 27, 2003

Ms. Robin Nazzaro
Director
Natural Resources and Environment
United States General Accounting Office
Washington, DC 20548

Dear Ms. Nazzaro:

Thank you for the opportunity to review the draft GAO report titled "University Research: Federal Agencies Need to Better Protect against Financial Conflicts of Interest" (GAO-04-31). We were pleased that the report included no recommendations for NASA. We were also pleased that you recognized the fact that we post abstracts of final technical reports on our Web site. Although we do post some technical reports now, we plan to increase the number offered in calendar year 2004.

The report included a recommendation that the National Science and Technology Council develop uniform federal requirements for universities and other federal funding recipients to identify and resolve financial conflicts of interest. NASA would certainly comply with any uniform federal requirements developed to identify and resolve such concerns.

If you have any questions or require additional information, please contact Thomas S. Luedtke, Assistant Administrator for Procurement, at (202) 358-2090.

Cordially,

Frederick D. Gregory
Deputy Administrator

Comments from the National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

OCT 30 2003

Ms. Robin Nazzaro
Director, Natural Resources and Environment
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Nazzaro:

We appreciate the opportunity to review this draft report. The report addresses your review objectives and provides a clear perspective of the uniqueness of NIH research grants and the challenges of providing the valuable results to the public.

In our comments we offer several technical suggestions and corrections for your consideration. We believe that incorporation of these will correct some inaccuracies and enhance the clarity of the final report.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

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